or a homolog thereof, wherein said homolog has an at least about 7 contiguous amino acid region identical in sequence to a 7 contiguous amino acid region of an amino acid sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:31, and SEQ ID NO:34.

REMARKS

I. Restriction Requirement under 35 U.S.C. § 121

The Examiner has restricted the present application into four groups of claims, as follows: Group I: (Claims 1-14) drawn to isolated proteins; Group II (Claim15) drawn to an antibody; Group III (Claims 20-22) drawn to a method of protecting an animal from disease; and Group IV (Claims 23-24) drawn to a method and kit to identify inhibitor compounds against astacin metalloendopeptidase. The Examiner noted that Claims 16-19 link Groups I and II, and would be examined as part of Groups I or II if either one of them is elected.

Applicants elect to prosecute Group I, and the linking claims, 16-19, as they apply to Group I, with traverse. This election is made solely in the interest of expediting prosecution. Applicants traverse the restriction between Groups I and III to the extent that Group III recites the subject matter of the elected group, as well as the restrictions between Groups I and IV and Groups I and II. The Patent Office may require restriction if two or more "independent and distinct" inventions are claimed in one application. However, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P. § 803. Applicants submit that a thorough search for Group I should also include the subject matter of

Groups II, III, and IV to the extent of the elected group. In the present case, the subject matter of these Groups cited by the Examiner, is sufficiently small and is so closely related as to be capable of examination together. The restriction requirements in this case only serve to increase the prosecution expense to the Applicants and to the Patent and Trademark Office.

More specifically, with regard to the restriction between Groups I and III, the claims of Group III are drawn to a method of protecting an animal from disease by administering an astacin metalloendopeptidase of Group I. Applicants submit that the method defined by Group III requires the use of the protein of Group I. Therefore, Applicants submit that Group I and Group III are so closely related that a thorough search for the subject matter of Group I would be sufficient to examine the claims of Group III to the extent that the Claims of Group III recite the subject matter of Group I.

With regard to the restriction between Groups I and IV, the claims of Group IV are drawn to a method and kit to identify inhibitor compounds against the astacin metalloendopeptidase of Group I. Applicants submit that the method defined by Group IV requires the use of the protein of Group I. Therefore, Applicants submit that Group I and Group IV are so closely related that a thorough search for the subject matter of Group I would be sufficient to examine the claims of Group IV to the extent that the Claims of Group IV recite the subject matter of Group I.

With regard to the restriction between Group I and Group II, the claim of Group II is drawn to an antibody that selectively binds to the protein claimed in Group I. Applicants submit that the claim of Group II concerns a molecule that is specifically defined by its relation to the protein of Group I. That is, there is a unique biological relationship between the isolated protein of Group I and the antibody of Group II. In *In re Gold*, 42 USPQ2d 1095 (Comm'r Pats.,

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unpublished) the Commissioner of Patents and Trademarks granted petitioner's request for withdrawal of a requirement for restriction between claims in a protein group and claims in an antibody group because the "patentable distinctness" issue was close. In *Gold*, the Commissioner considered restriction of an antibody claim that depended from a peptide claim. Here, the claimed antibody of Group II depends from the claimed protein of Group I. Applying the Commissioner's ruling in *Gold*, the "patentable distinctness" between the claimed antibody of Group II and the protein of Group I is sufficiently close to warrant the withdrawal of the restriction requirement. Applicants respectfully submit that the "patentable distinctness" of the two claimed groups is close because the two claimed groups are biologically related and thereby not independent.

In view of the foregoing arguments, Applicants respectfully request that the Examiner withdraw the restrictions between Groups I and III, Groups I and IV, and Groups I and II. If the Examiner does not withdraw the restriction, applicants reserve the right to traverse restrictions between Groups II-IV in subsequent divisional applications. Applicants also reserve the right to file a divisional application relating to these claims without the necessity of filing a terminal disclaimer.

In any event, if the elected claims of Group I are allowable, Applicants reserve their right to amend the claims of Group III and IV to be commensurate in scope with the product claims of Group I, and to request that the claims of Group III and IV that depend from or otherwise include all the limitations of the allowable product be rejoined and examined for patentability. *In re Brouwer*, 37 USPQ2d 1663 (Fed. Cir. 1996); *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995).

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II. The Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 10, 14, and 19 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claims 10 and 14 have been canceled thereby rendering the rejection of those claims moot. Claim 19 has been rejected for the recitation of the phrase "comprises heartworm disease." Claim 19 has been amended to overcome this rejection by describing a therapeutic composition that protects an animal from heartworm infection.

In view of the foregoing amendments and remarks, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

III. The Rejection Under 35 U.S.C. § 112, First Paragraph

a. Claims 1-7, 9, 12-14, and 16-19 have been rejected under 35 U.S.C. § 112, first paragraph for failure to provide sufficient description for a claimed genus. Claims 2-7, 9, and 14 have been canceled thereby rendering the rejection of those claims moot. Claim 1 has been amended to include relevant functional and structural characteristics to overcome this rejection. The first characteristic is the ability to elicit an immune response against an astacin metalloendopeptidase having a specified amino acid sequence. The second characteristic is that the protein is encoded by a nucleic acid molecule, the complement of which hybridizes under stringent conditions with a nucleic acid molecule having a specified sequence. In order to further clarify the invention, Applicants have also added new Claim 25 which claims proteins with specific amino acid sequences, or a homologs of those proteins which have an at least about 7 contiguous amino acid region identical in sequence to a 7 contiguous amino acid region of the specific sequences. Support for these changes is found at pp. 25-26, 35, 41, 44-45, and 77-79. Claim 16

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has been similarly amended to recite descriptions of proteins and to recite that the claimed antibody selectively binds to a protein comprising a *D. immitis* astacin metalloendopeptidase protein. It is believed that Claim 1, Claim 16, Claim 25, and all dependent claims therefrom are now sufficiently descriptive to overcome this rejection.

b. Claims 1-7, 9-14, and 16-19 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use metalloendopeptidases beyond that from *D. immitis*. Claims 2-7, 9, 10, and 14 have been canceled thereby rendering the rejection of those claims moot. Claims 1 and 16 have been amended to provide a description of the claimed protein in functional and structural terms. Claim 11 has also been amended in this manner, and now contains descriptive structural and functional characteristics. The claimed proteins are defined by sequence, and the claimed portions must also elicit an immune response against a protein defined by sequence. In order to further clarify the invention, Applicants have also added new Claim 25 which claims proteins with specific amino acid sequences, or a homologs of those proteins which have an at least about 7 contiguous amino acid region identical in sequence to a 7 contiguous amino acid region of the specific sequences. Support for these changes is found at pp. 14-15, 25-26, 35, 41, 44-45, and 77-79.

The Examiner objects that the predictability of success in using the disclosed sequences to produce additional nucleic acids is extremely low given the large number of potential nucleic acids to be tested. Applicants traverse this rejection and submit that the amount of experimentation required to identify the proteins claimed in the present application is not dispositive of undue experimentation. A considerable amount of experimentation is permissible if it is merely routine,

or the specification provides reasonable guidance regarding the direction that experimentation is to proceed. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); M.P.E.P. § 2164.06. Not only is it known by one skilled in the art how to identify additional proteins using specified nucleic acid molecules and proteins of the present invention, but the specification also provides detailed procedures for practicing the invention. For example: Example 1 teaches the presence of astacin metalloendopeptidases in the parasite helminth *D. immitis*. Example 2 teaches the use of *D. immitis* DNA to isolate nucleic acid molecules that are less than or equal to 30% base pair mismatched and the identification of astacin metalloendopeptidase encoding nucleic acids. Examples 3-5 describe the incorporation of the nucleic acids into recombinant molecules and cells in order to produce astacin metalloendopeptidase proteins of the present invention. Examples 6 and 7 describe the cloning and sequencing of additional nucleic acid molecules from larval and adult parasite DNA, as do pages 43-44. The specification further teaches how to determine if a protein elicits an immune response at pp. 14-15 and 77-79. Applicants respectfully submit that the specification provides the necessary guidance to one skilled in the art wishing to practice the invention.

c. Claims 10 and 11 have been rejected for lack of enablement for the use of the invention claimed therein. Claim 10 has been canceled, thereby making the rejection of Claim 10 moot. Claim 11 has been amended to provide a description of the claimed protein in functional and structural terms. The claimed proteins are defined by sequence, and the claimed portions must also elicit an immune response against a protein defined by sequence. Support for these changes is found at pp. 14-15, 35, and 77-79. These pages describe the sequences and teach how to elicit an immune response. The specification further defines "at least a portion of" at p. 15. It

is believed that the amendment to Claim 11 is sufficiently descriptive to overcome the rejection, as it known by one skilled in the art how to identify proteins that effect an immune response.

In view of the foregoing amendments and remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph be withdrawn.

IV. The Objection to Claim 8

Claim 8 has been objected to as being dependent upon a rejected base claim, but the Examiner indicated that it would be allowable if rewritten in independent form. Claim 8 has been so amended.

In view of the foregoing amendments and remarks, Applicants submit that all pending claims are in condition for allowance. Consideration of the above and withdrawal of all rejections are hereby requested. No fees are believed to be due with this Amendment and Response; however, if fees are due, please debit Deposit Account No. **19-1970**. In the event that the Examiner has any questions regarding Applicants' position, the Examiner is invited to contact the below named Patent Attorney at (303) 863-9700.

Respectfully submitted,

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Gary J. Connell
Registration No. 32,020
Sheridan Ross P.C.
1700 Lincoln St., Suite 3500
Denver, Colorado 80203-4501
Telephone: (303) 863-9700
Facsimile: (303) 863-0223/0225

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